



### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

JEFFREY S. KIEL

Serial No.:

10/505,347

Group Art Unit: 1615

Filed:

August 19, 2004

For:

DIPHENHYDRAMINE TANNATE SOLID DOSE COMPOSITIONS AND METHODS OF USE

### **INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

Applicant discloses to the Examiner under 37 CFR 1.56, and 37 CFR 1.97-1.98, as revised (1135 OG 13) and effective March 16, 1992, the information listed on the attached form PTO - 1449. This information may be found to be material to this invention under the current applicable patent law and as interpreted by the US PTO Rules, as cited above. Review and consideration of the listed references/information during substantive examination of this application is respectfully requested.

Applicant specifically emphasizes that this statement, and/or the act of identifying this information, is not to be construed as an admission that all or any of it is prior art to

the specific invention disclosed and claimed. Also nothing in this statement is to be construed as a representation that this is the only material information to be found, or the best. If additional material information is discovered in the future, a prompt submission will be made to fulfill applicant's continuing duty of disclosure under 37 CFR 1.56.

Respectfully submitted,

KING & SCHICKLI, PLLC

Warren D. Schickli

Registration No. 31,057

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#### **CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

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PTO/SB/08A (10-01)
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Substitute for form 1449A/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet of

Complete if Known				
Application Number	10/505,347			
Filing Date	08/19/2004			
First Named Inventor	JEFFREY S. KIEL			
Art Unit	1615			
Examiner Name				
Attorney Docket Number	455-020			

				U.S. PATE	ENT DOCUMENTS	
Examiner Initials	Cite No.1		nt Number ind Code <sup>2</sup> (if known	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	us- 6	,306,904	10/23/2001	GORDZIEL	
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Examiner		Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages			
Initials	No.1	Country Code 3 - Number 4 - Kind Code 5 (if known)	MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	Т6		
		,						

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		US-						
		US- US-						
		US-						

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 First Named Inventor
 JEFFREY S. KIEL

 Group Art Unit
 1615

 Examiner Name
 455-020

nitials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	1	CYPRESS PHARMACEUTICAL, INC., "R-Tannic-S A/D," RX Only, Cypress Pharmaceutical, Inc., (Madison, MS), p. 1, 2 (March 1, 2001).
	2	DSC LABORATORIES, "Phenylephrine Tannate/Pyrilamine Tannate Suspension," RX Only, DSC Laboratories (Muskegon, MI), p. 1, 2 (Aug. 1, 2001).
	3	RONALD GOLDBERG, M.D. and FRANKLIN SHUMAN, M.D., "Evaluation of a Prolonged Action Oral Antihistaminic Preparation as Treatment for Allergic Disorders," Clinical Report, Clinical Medicine (Washington), Vol. 72 (No. 9), pp. 1475-1479 (Sept. 1, 1965).
	4	JOHN WEILER, M.D. ET AL., "Randomized, double-blind, parallel groups, placebo-controlled study of efficacy and safety of Rynatan in the treatment of allergic rhinitis using an acute model," Annals of Allergy, ACAI (Iowa City, IA), Vol. 64 (No. 1), p. 63-67 (Jan. 1, 1990).
	5	(455-016) U.S. Patent Application No. 10/119,285 filed 04/09/2002: "Process for Preparing Tannate Liquid and Semi-Solid Dosage Forms" (Notice of Allowance has been issued)
	6	(455-016 CONT) U.S. Patent Application No. 10/921,438 filed 08/19/2004: "Process for Preparing Tannate Liquid and Semi-Solid Dosage Forms"
	7	(455-017) U.S. Published Patent Application No. US2003/0077321 A1 published on April 24, 2003: "Process for Preparing Tannate Tablet, Capsule or other Solid Dosage Forms"
	8	(455-020) U.S. Patent Application No. 10/505,347 filed 08/19/2004: "Diphenhydramine Tannate Solid Dose Compositions and Methods of Use"
	9	(455-021) U.S. Published Patent Application No. US/2004/0234593 published on November 25, 2004: "Diphenhydramine Tannate Compositions and Methods of Use"
	10	(455-030) U.S. Patent Application No. 10/799,302 filed 03/12/2004: "Single Tank Process For Preparing Tannate Liquid and Semi-Solid Dosage Forms"

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